

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

ANDREA MELTON,

Plaintiff,

Case No. 3:11oe 40009

-vs-

ORTHO-MCNEIL PHARMACEUTICAL, INC.,
et al.,

AMENDED
MEMORANDUM OPINION

Defendant.

KATZ, J.

Plaintiff Andrea Melton sued Defendants when she experienced a pulmonary embolism after using Defendants' Ortho Evra® birth control patch. Currently pending is Defendants' combined motion for summary judgment and judgment on the pleadings as to all of Plaintiff's claims. (Doc. 17). For the reasons that follow, Defendants' motion is granted in part and denied in part.

I. Background

Plaintiff was prescribed the Ortho Evra® birth control patch by William P. Long, D.O., who is board certified in obstetrics and gynecology. The record reflects that at the time Dr. Long prescribed the patch to Plaintiff, he was informed of Ortho Evra®'s risks and was familiar with Ortho Evra®'s package insert, including the detailed patient labeling, which specifically warned of, *inter alia*, increased risk of a pulmonary embolism. Dr. Long was also familiar with the Dear Healthcare Professional Letter ("DHCP") from Ortho's Women's Health and Urology, which includes information regarding the risks of Ortho Evra®. Further, Dr. Long testified that he prescribed Ortho Evra® for Plaintiff because he believed its benefits outweighed its risks.

Plaintiff used the patch from July 2008 until December 11, 2008, when she experienced a pulmonary embolism. Plaintiff subsequently filed this action as part of the Ortho Evra® multidistrict litigation. Defendants now move for summary judgment and judgment on the pleadings.

II. Legal Standards

A. Summary Judgment

Summary judgment is appropriate where “the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c). The moving party bears the initial responsibility of “informing the district court of the basis for its motion, and identifying those portions of ‘the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,’ which it believes demonstrate the absence of a genuine issue of material fact.” *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 106 S. Ct. 2548, 2553, 91 L. Ed. 2d 265 (1986). The movant may meet this burden by demonstrating the absence of evidence supporting one or more essential elements of the non-movant’s claim. *Id.* at 323-25. Once the movant meets this burden, the opposing party “must set forth specific facts showing that there is a genuine issue for trial.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250, 106 S. Ct. 2505, 2541, 91 L. Ed. 2d 202 (1986) (quoting FED. R. CIV. P. 56(e)).

Once the burden of production has so shifted, the party opposing summary judgment cannot rest on its pleadings or merely reassert its previous allegations. It is not sufficient “simply [to] show that there is some metaphysical doubt as to the material facts.” *Matsushita Elec. Indus.*

Co. v. Zenith Radio Corp., 475 U.S. 574, 586, 106 S. Ct. 1348, 1356, 89 L. Ed. 2d 538 (1986). Rather, Rule 56(e) “requires the nonmoving party to go beyond the pleadings” and present some type of evidentiary material in support of its position. *Celotex*, 477 U.S. at 324, 106 S. Ct. at 2553; *see also Harris v. General Motors Corp.*, 201 F.3d 800, 802 (6th Cir. 2000). Summary judgment must be entered “against a party who fails to make a showing sufficient to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial.” *Celotex*, 477 U.S. at 322, 106 S. Ct. at 2552.

“In considering a motion for summary judgment, the Court must view the facts and draw all reasonable inferences therefrom in a light most favorable to the nonmoving party.” *Williams v. Belknap*, 154 F. Supp. 2d 1069, 1071 (E.D. Mich. 2001) (citing *60 Ivy Street Corp. v. Alexander*, 822 F.2d 1432, 1435 (6th Cir. 1987)). However, “at the summary judgment stage the judge’s function is not himself to weigh the evidence and determine the truth of the matter,” *Wiley v. U.S.*, 20 F.3d 222, 227 (6th Cir. 1994) (quoting *Anderson*, 477 U.S. at 249); therefore, “[t]he Court is not required or permitted . . . to judge the evidence or make findings of fact.” *Williams*, 154 F. Supp. 2d at 1071. The purpose of summary judgment “is not to resolve factual issues, but to determine if there are genuine issues of fact to be tried.” *Abercrombie & Fitch Stores, Inc. v. Am. Eagle Outfitters, Inc.*, 130 F. Supp. 2d 928, 930 (S.D. Ohio 1999). Ultimately, this Court must determine “whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law.” *Anderson*, 477 U.S. at 251-52; *see also Atchley v. RK Co.*, 224 F.3d 537, 539 (6th Cir. 2000).

B. Judgment on the Pleadings

The Court construes Plaintiff's motion to dismiss as a Fed. R. Civ. P. 12(c) motion for judgment on the pleadings.

A Fed. R. Civ. P. 12(c) motion for judgment on the pleadings is analyzed under the same standard as a Fed. R. Civ. P. 12(b)(6) motion to dismiss. *Sensations, Inc. v. City of Grand Rapids*, 526 F.3d 291, 295 (6th Cir.2008). To defeat such a motion, the complaint must state sufficient facts, accepted as true, to state a claim "that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

In deciding the motion, the Court must accept as true all of the non-movant's factual allegations. *Erickson v. Pardus*, 551 U.S. 89, 94 (2007); *Thurman v. Pfizer, Inc.*, 484 F.3d 855, 859 (6th Cir. 2013). The complaint "need not contain 'detailed' factual allegations, [but] its 'factual allegations must be enough to raise a right to relief above the speculative level . . .'" *Ass'n of Cleveland Fire Fighters v. City of Cleveland, Ohio*, 502 F.3d 545, 548 (6th Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). Conclusory allegations and legal conclusions masquerading as factual allegations will not suffice. *Twombly*, 550 U.S. at 555 (holding that a complaint must contain more than "a formulaic recitation of the elements of the cause of action").

III. Discussion

A. Statutes of Limitation

Defendants move for summary judgment on grounds that "product liability claims brought under either a strict liability or negligence theory must be filed within two (2) years after the cause of action accrues." (Defs.' Br. Supp. Mo. Summ. J., Doc. 17-4 at 20) (citing 735 Ill. Comp. Stat.

5/13-202 (negligence claims); 735 Ill. Comp. Stat. 5/13-213(b) and (d) (strict liability claims); *Golla v. Gen. Motors Corp.*, 657 N.E.2d 894 (Ill. 1995)).

At the outset, the Court notes that while Defendants argue Plaintiff's strict liability and negligence-based products liability claims are barred by two year statutes of limitation, Defendants do not specifically state whether they believe Plaintiff's breach of express and implied warranty claims, or whether Plaintiff's sundry fraud claims are also governed by a two year limitations period. Regarding breach of implied warranty, it is clear from the Illinois Supreme Court's decision in *Berry v. G.D. Searle & Co.*, 309 N.E.2d 550 (Ill. 1974), that Plaintiff's breach of implied warranty claim is governed by a four year limitations period and is therefore timely. See *Berry*, 309 N.E.2d at 554 (holding in a personal injury suit deriving from use of birth control pills that "section 2-725(1) sets forth the appropriate limitation period [4 years] for personal injury actions predicated upon a breach-of-implied-warranty theory under the Code."). As to Plaintiff's breach of express warranty and fraud claims, Defendants do not argue the appropriate limitations period and therefore have not shown they are entitled to judgment as a matter of law.

Turning to Plaintiff's strict liability and negligence-based claims, Defendants are correct that the claims are untimely. As explained by *Golla, supra*, Sections 13-202 and 13-213 apply a two year limitations period to strict liability and negligence-based product liability claims. *Golla*, 657 N.E.2d at 896. Importantly, the "discovery rule" can postpone the commencement of the statutes of limitation "until the injured plaintiff knows or reasonably should know that he has been injured and that his injury was wrongfully caused." *Id.* at 898 (citing *Rozny v. Marnul*, 250 N.E.2d 656, 665-66 (Ill. 1969) (establishing discovery rule)). The discovery rule does not apply, however, "where the plaintiff's injuries are caused by a sudden traumatic event." *Golla*, 657

N.E.2d at 898 (citing *Williams v. Brown Mfg. Co.*, 261 N.E.2d 305 (Ill. 1970)). In such cases, the cause of action accrues when the injury occurs. *Id.*

In the instant matter, Plaintiff's injury was caused by a sudden traumatic event and Plaintiff's claims therefore accrued at the time of injury. *Berry, supra*, is instructive. In that case, the plaintiff maintained she did not find out for more than two years that her injuries—permanent paralysis caused by a stroke—were caused by consumption of birth control pills. Despite this, the Illinois Supreme Court found the two year statute of limitations began running from the date of injury because the “plaintiff’s description of the severity of her condition in the complaint and her reply brief [which included statements that “she ‘knew she was ill, that she had suffered a stroke and was partially and permanently paralyzed’”] [made it] inconceivable that her injury was not occasioned by a traumatic event.” *Berry*, 309 N.E.2d at 559. Similarly, in this case Plaintiff stated at deposition that she went to the emergency room with symptoms of dizziness and shortness of breath, whereupon she was told she “was not allowed to move an inch on [her] own,” and that she needed to be transferred to a different hospital to have access to blood thinners and to the ICU. (Plf’s. Dep., Doc. 18-7 at 179:11-18, 180:15-182:9). At the new hospital Plaintiff was told she had “a massive pulmonary embolism.” *Id.* at 183:7-10. Thus, the evidence reflects that Plaintiff’s injury was occasioned by a sudden traumatic event, and Plaintiff’s cause of action therefore accrued at the time of her injury on December 11, 2008. Since Plaintiff did not file this action until August 18, 2011—more than two years later—her strict liability and negligence-based product liability claims are barred by the statute of limitations.

B. Summary Judgment on Failure to Warn

Defendants move for summary judgment against Plaintiff's failure to warn claims.

Defendants argue the claims are barred by Illinois' learned intermediary doctrine because Plaintiff's physician, Dr. Long, was fully apprised of the risks associated with Ortho Evra® when he prescribed the drug for Plaintiff. In any event, Defendants argue their warnings were adequate as a matter of law and, as such, Plaintiff cannot prove her *prima facie* case. Defendants are correct on both issues, and the Court will therefore grant summary judgment against Plaintiff's failure to warn claims.

Regarding the learned intermediary doctrine, “[a]n adequately informed physician acts as learned intermediary between the patient and the drug manufacturer, thus breaking the chain of liability.” *Ashman v. SK&F Lab Co.*, 702 F. Supp. 1401, 1404 (N.D. Ill. 1988). “[I]f it is not a genuine issue that the prescribing physician was aware of the risks associated with the drug, then the manufacturer is entitled to summary judgment.” *Koncz v. Burroughs Wellcome Co.*, No. 92 C 5797, 1994 U.S. Dist. LEXIS 6014, at *7 (N.D. Ill. May 6, 1994). “[T]he manner in which the physician becomes informed is irrelevant.” *Id.* at *8. In the instant matter, Defendants' Ortho Evra® package insert and detailed patient labeling, as well as Defendants' Dear Healthcare Professional (“DHP”) Letter, explicitly warned of the exact adverse events suffered by Plaintiff; namely, increased risk of developing blood clots and pulmonary embolism as a result of Ortho Evra®'s increased estrogen levels. Moreover, Dr. Long testified at deposition that he was familiar with these materials, and further testified that prior to prescribing Plaintiff's Ortho Evra® he was aware that the drug exposes users to sixty percent more estrogen over a thirty-five microgram estrogen pill. Further, Dr. Long testified he is aware Ortho Evra® can double the risk of blood

clots. Because Dr. Long was aware of these risks prior to prescribing Plaintiff's Ortho Evra®, Defendants are entitled to summary judgment under Illinois' learned intermediary doctrine.

Defendants are also entitled to summary judgment against Plaintiff's failure to warn claims because the warnings at issue are adequate as a matter of Illinois law. *Kelso v. Bayer Corp.*, 398 F.3d 640 (7th Cir. 2005), is instructive. In that case, the Seventh Circuit affirmed summary judgment, holding that the defendant drug manufacturer's warning was adequate as a matter of law "because [it] clearly and explicitly warned consumers not to use [the drug] for more than *three days . . .*" *Id.* at 643 (emphasis in original). The *Kelso* court also found the defendant's warnings adequate as a matter of law because they complied with FDA-required warnings. *Id.* Similarly, Defendants' warnings in the instant matter are adequate as a matter of law because they warned of the specific adverse effects suffered by Plaintiff and because they were part of an FDA-approved package insert.

C. Judgment on the Pleadings as to Non-Failure to Warn Claims

Defendants move for Fed. R. Civ. P. 12(c) judgment on the pleadings as to Plaintiff's claims for negligence, breach of express and implied warranty, and fraud. Defendants' motion will be denied.

Defendants' reply brief claims that since Plaintiff contends all theories of recovery are predicated on Defendants' alleged failure to warn, the learned intermediary analysis, *supra*, requires judgment on the pleadings on all claims, even on Plaintiff's non-failure to warn claims. Importantly, it is improper for Defendants to raise this issue for the first time in their reply brief. See *Scottsdale Ins. Co. v. Flowers*, 513 F.3d 546, 553 (6th Cir. 2008) (explaining reply briefs allow moveant to reply to opposition's arguments, not raise new arguments in support of motion).

In any event, Defendants do not provide the Court with any explanation or authority as to why non-failure to warn claims are barred by a doctrine designed to preclude failure to warn claims. Defendants' unsupported, passing assertion neither offers a meaningful analysis, nor a basis on which to grant judgment on the pleadings.

Defendants also move for judgment on the pleadings on grounds that Plaintiff's complaint contains insufficient factual allegations and therefore amounts to the sort of formulaic recitation of the elements precluded under *Twombly*, 550 U.S. at 555. Upon review, the Court finds Plaintiff's complaint is not violative of the Federal Rules' pleading standards. Rather, Plaintiff's complaint states sufficient factual matter to put Defendants on notice as to the nature of her claims, and to state claims that are plausible on their face. *See Ortho Evra Prods. Liab. Master Compl.*, Doc. 18-4; *see also* Fed. R. Civ. P. 8(a) (pleading must contain short plain statement of claim showing pleader is entitled to relief); *Twombly*, 550 U.S. at 555 (Rule 8(a) requires that complaint contain sufficient factual matter to establish claim that is plausible on its face); *accord Iqbal*, 556 U.S. at 678. Further, Plaintiff pleads her fraud claims with sufficient particularity to satisfy Fed. R. Civ. P. 9(b)'s heightened pleading standard.

Finally, Defendants argue they are entitled to judgment on the pleadings as to Plaintiff's breach of implied warranty claim because there is no privity of contract between Plaintiff and Defendants. No privity is required under Illinois law, however, where, as here, Plaintiff brings a tort suit for personal injury. *See Berry v. G.D. Searle & Co.*, 309 N.E.2d 550, 556 (Ill. 1974) (holding in a personal injury suit deriving from use of birth control pills that "we are of the opinion that privity is of no consequence when a buyer who purportedly has sustained personal

injuries predicates recovery against a remote manufacturer for breach of an implied warranty under the Code.”).

In summary, Defendants’ motion for judgment on the pleadings is denied.

IV. Conclusion

For the reasons stated herein, Defendants’ motion for summary judgment is granted in part and denied in part. (Doc. 17). The motion is granted as to Plaintiff’s strict liability failure to warn claim, and as to Plaintiff’s negligence-based product liability claims. Defendants’ motion for summary judgment is denied as to all other claims.

Further, Defendants’ motion for judgment on the pleadings is denied. (Doc. 17).

IT IS SO ORDERED.

s/ David A. Katz
DAVID A. KATZ
U. S. DISTRICT JUDGE